

**HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT**

“EPA’s IRIS Program: Reviewing Its Progress And Roadblocks Ahead”

Questions for the Record to:

Jennifer Orme-Zavaleta, Ph.D.

**Principal Deputy Assistant Administrator for Science and EPA Science Advisor
Office of Research and Development
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Submitted by Subcommittee Chairwoman Mikie Sherrill (D-NJ)

1. In the fall of 2018, David Dunlap assumed the role of deputy assistant administrator of ORD. Around the same time, ORD initiated the second round of the survey process, which you said you had no involvement in, though you had disseminated the first round. Did the process switch from your purview to David Dunlap’s, and if so, when? What was his involvement in compiling the December 2018 and the April 2019 Program Outlook documents? What was yours? Was David Dunlap involved in decisions relating to formaldehyde prior to his December 2018 recusal?

A: In her role as Principal Deputy Assistant Administrator of the Office of Research and Development (ORD), Dr. Jennifer Orme-Zavaleta was not involved in the second round of prioritization; ORD received the final lists of program office priority assessments. As such, Principal Deputy Assistant Administrator Orme-Zavaleta cannot speak to ORD Deputy Assistant Administrator David Dunlap’s involvement in the second round of prioritization or decisions relating to formaldehyde.

Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program’s Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency’s Assistant Administrators and Deputies. The April 2019 Program Outlook was posted by IRIS program staff and reflected the priority assessments identified in December 2018.

2. In the April 2019 Program Outlook, EPA lists some chemicals as “discontinued” and some as “suspended.” What is the distinction between these classifications? What does it mean that assessments of suspended chemicals may be “restarted as Agency priorities change?” How does this differ from how work on a currently discontinued chemical may be picked up in response to changing priorities?

A: “Discontinued” assessments are those for which the IRIS program is not planning to develop new or updated assessments at this time. This means that we do not anticipate these to become Agency IRIS priorities in the near future. These include hexabromocyclododecane (HBCD), acrylonitrile, n-butyl alcohol, and phthalates (butyl benzyl phthalate, dibutyl phthalate, diethyl phthalate, di-isobutyl phthalate, and di-isononyl phthalate).

“Suspended” assessments are those that have been placed on hold and may be restarted as Agency priorities change. This means that we are prepared for future Agency needs. The assessments suspended in the April 2019 Program Outlook include ammonia, chloroform, ethylbenzene, formaldehyde, manganese, naphthalene, nitrite/nitrate, PAH mixtures, and uranium.

Draft assessment materials previously released on the IRIS program website will remain accessible for reference on individual chemical pages. Additionally, existing toxicity values found on IRIS will remain available for use. More information about these chemicals can be found on the IRIS program website.

3. According to your testimony, OCHP submitted its final list of priority chemicals for the IRIS survey exactly one day after ORD released a Program Outlook for the IRIS program in December 2018. As a result, ORD did not incorporate OCHP’s priorities into the official IRIS Program Outlook. As it was compiling the December 2018 Program Outlook, did ORD make any effort to obtain OCHP’s second-round survey response? What internal communications, written or oral, did OCHP receive regarding the timing and/or content of this second-round survey? Which EPA offices and officials communicated with OCHP regarding the IRIS survey, and to whom at OCHP were they communicating?

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program’s Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

Through this new process, EPA programs and regions can formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. As detailed in the December 4, 2018 memorandum from Principal Deputy Assistant Administrator Orme-Zavaleta, ORD consolidated the program and region input on high priority assessment needs and presented this to the Agency's Assistant Administrators and Deputies. Based on that input, this prioritization process identified eleven priority chemicals: hexavalent chromium, inorganic arsenic, mercury salts, methylmercury, polychlorinated biphenyl (PCBs), five per- and polyfluoroalkyl substances (PFAS), and vanadium. The IRIS program will conduct this same formal request and prioritization process annually, but programs and regions are still able to identify and nominate additional chemicals at any time.

4. In September 2018, the Director of OCHP was placed on Administrative Leave. Please identify the career employee or employees at OCHP who oversaw the compilation of OCHP's final list of priority chemicals for the IRIS survey. Please also identify the official who possessed the ultimate authority to approve OCHP's final list of priority chemicals before it was submitted to ORD.

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

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5. What chemicals did OCHP submit on its final priority list for the IRIS survey? Was formaldehyde one of the chemicals that OCHP identified as a priority?

A: Because IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources, Principal Deputy Assistant Administrator Orme-Zavaleta, at the direction of then-Acting Administrator Wheeler, in a request dated August 10, 2018, established a more formal, structured process for identifying IRIS priorities. This process included a requirement that all IRIS priorities be approved by the program's Assistant Administrator. This initial formalized prioritization process was completed in December 2018, and it is bringing further stability and responsiveness to the IRIS program.

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6. If OCHP had submitted its final list of priority chemicals for the IRIS survey before December 4, 2018, would its priorities have been included in the IRIS Program Outlook for December 2018? Since OCHP submitted its final list of priority chemicals too late to be considered as a part of the 2018 IRIS survey, will its priorities now be considered immediate nominations for the IRIS program, or as nominations for the next IRIS priority survey? Were these responses considered in ORD's April 2019 Program Outlook?

A: OCHP submitted priorities after the list of priority IRIS assessments had been finalized. This final list informed the April 2019 Program Outlook.

The EPA will conduct its annual IRIS priority survey later this year. At that time, EPA program offices will have the opportunity to formally nominate their priority chemicals, but program offices may nominate a chemical for IRIS at any time.

7. According to Dr. Orme-Zavaleta's testimony, the IRIS priority survey will now occur annually. Please elaborate on how ORD plans to conduct the IRIS survey in 2019, and whether any procedures will differ from the process that occurred in 2018. When will the

2019 survey formally begin, and how will ORD ensure that every program office in EPA possesses the opportunity to submit its priorities in time to be considered?

A: Through ORD, the Agency will conduct its IRIS priority survey annually and plans to begin this process in summer 2019. The EPA plans to conduct this process similar to that which occurred in August 2018, with a memo from ORD leadership to the EPA program offices. The memo will include the standardized prioritization template for nominating IRIS assessments, and the memo will clearly state the purpose, type of assessment needed, and deadlines. This will ensure every program office has the opportunity to submit its priorities.

8. How much money has been spent over the years in preparing the draft formaldehyde assessment that is reportedly ready to be released for review?

A: Formaldehyde, because of the complexity and volume of data, is primarily an FTE investment. In addition to the FTE investment, EPA costs associated with IRIS assessments include workshops, contractor support, and NAS peer review, among other expenses.

Submitted by Representative Don Beyer (D-VA)

9. The GAO report issued on March 4, 2019, stated that it was unclear what the IRIS prioritization process was meant to achieve. What was the purpose of the prioritization process? Who was involved in the decision to undertake each step of the prioritization process, from May 2018 through April 2019?

A: IRIS assessments play a critical role in supporting Agency decisions and can involve a significant expenditure of time and resources. Because of the IRIS program's importance, IRIS program staff initiated a review of IRIS priorities at the staff level in May 2018. Then-Acting Administrator Wheeler requested a more formal, structured survey of IRIS priorities in July to be signed at the Assistant Administrator level. This formalized prioritization process was completed in December 2018, and it is bringing further stability and accountability. Through this new process, EPA programs formally identify what assessments are a priority program need, why the assessment is needed, and when the assessment is needed. Not only does this improve the scope of IRIS assessments and help the IRIS program prioritize its activities, it also reinforces accountability between the requesting program and the IRIS program.

Through ORD leadership, the Agency initiated the first survey of IRIS program priorities in August 2018. ORD was not involved in the EPA program offices' further prioritization efforts.

Submitted by Representative Bill Foster (D-IL)

Willowbrook Illinois in my district is home to a sterilization facility that used Ethylene Oxide to sterilize medical equipment. This community has unfortunately become an example of the important role the EPA plays in defending public health and what can happen when these systems do not work as they should. In the case of Ethylene Oxide, there was a 15-year gap between the publication of scientific papers that indicated that EtO was a far more powerful carcinogen than had been previously assumed, and the corrective actions and eventual shutdown of the facility in my district that was venting apparently unsafe amounts of EtO into nearby neighborhoods. See Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (CASRN 75-21-8) and references therein.

10. What were the reasons for a 15-year delay in this type of situation?

A: The IRIS ethylene oxide assessment, which was initiated in 2002, took about 15 years to complete because of the complexity of the data that needed to be evaluated, as well as the peer review process to which this assessment was subjected. The current assessment reflects the IRIS program's evaluation of the best available science published through 2015 on the health hazards associated with ethylene oxide exposure.

Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.

11. How much of that delay could have been avoided if the EPA and other relevant regulators had been adequately and fully staffed and funded during this period?

A: Ethylene oxide is a chemical with a large and robust literature of human epidemiology data. These data are often more complex and time-consuming to analyze compared with data from animal studies. Moreover, the EPA needed to gain access to the original data from one of the key epidemiology studies to conduct

specific analyses recommended by external peer reviewers. During the first peer review conducted by the EPA's Science Advisory Board (SAB) in 2006, the reviewers specifically recommended that the EPA conduct original dose-response modeling of the individual epidemiology data using approaches that the EPA had not previously used. This recommendation resulted in a significant amount of new work in revising the assessment. Then, given the significant additional modeling of the epidemiologic data, the revised assessment underwent a second peer review in 2012, because the EPA was aware of the critical importance of ethylene oxide, both in terms of its potential human health risk and its importance as a sterilization agent and a feedstock chemical. It is important to note that the ethylene oxide assessment is somewhat unique and that since 2016, the EPA has significantly streamlined its assessment development processes and timelines.

12. What is the best estimate of the number of people that will eventually get cancer, nationwide, because of that delay?

A: An IRIS assessment addresses only the first two (of four) steps of the risk assessment process; the reference values derived in an IRIS assessment describe the quantitative relationship between dose or concentration and the effect. An IRIS assessment alone cannot be used to predict health risk (or number of cases of cancer) in a population.